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09/366,458	08/03/1999	WILLIAM J. DREYER	CIT1150-1	3096

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EXAMINER
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HUNT, JENNIFER ELIZABETH

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/366,458

Applicant(s)

Dreyer

Examiner

Jennifer Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 31, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 50-57 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 50-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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***Response to Amendment***

1. Acknowledgment is made of applicant's cancellation of claims 11-49, and addition of new claims 50-57. Claims 1-10 and 50-57 are pending in the application and considered herein.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. This is a non-final Office Action.

***Specification***

4. The objection to the disclosure for containing embedded hyperlinks is withdrawn in light of the amendments thereto.

***Claim Rejections Withdrawn***

5. The rejection of claims 1-10 as unclear in the recitation of "serpentine cell surface marker," is withdrawn in light of the amendments thereto.
6. The rejection of claims 2-3 as unclear in the recitation of a marker which is "associated with" a specific cell type, is withdrawn in light of the amendments thereto.
7. The rejection of claims 2-3 as unclear in the recitation of a marker which is "selecting for" an additional marker is withdrawn in light of the amendments thereto.

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8. The rejection of claims 7-9 as unclear in the recitation of "analyzing the DNA" is withdrawn in light of the amendments thereto.
9. The rejection of claims 7-9 as incomplete because they omit essential steps is withdrawn in light of the amendments thereto.
10. The rejection of claims 1-10, under 35 U.S.C. 112, first paragraph, for lacking the full scope of enablement is withdrawn in light of the amendments thereto.

***Claim Rejections Maintained***

11. The rejections of claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are maintained for reasons set forth below.
12. The rejection of the term "substantially enriched" in claims 1-10, as a relative term which renders the claim indefinite is maintained for reasons of record, and applied to newly added claims 50-57.

Applicant argues that there is no requirement that a specific level for "substantially" be specified. Applicant's arguments filed 12/31/2001 have been fully considered but they are not persuasive.

As set forth in the previous office action, the term "substantially enriched" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree,

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and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, it cannot be determined how enriched a composition must be to be considered "substantially" enriched. That is, at what point of "enrichment" is a composition "substantially enriched" as opposed to just "enriched?"

13. The rejection of claims 1-10 as unclear in the recitation of "binding agent" is maintained for reasons of record, and applied to newly added claims 50-57. The metes and bounds of a "binding agent" cannot be determined.

Applicant argues that the specification provides adequate guidance for the term "binding agent." Applicant's arguments filed 12/31/2001 have been fully considered but they are not persuasive.

As set forth in the previous office action, it is not clear what would be considered a "binding agent" and what would not. Specifically, the qualities and properties of a binding agent are unclear; at what specificity affinity, and selectivity must any of the innumerable possible agents bind to something, in order to be considered a binding agent?

14. The rejection of claim 5 as unclear in the recitation of "or derivative thereof" is maintained for reasons of record. The metes and bounds of a derivative cannot be determined.

Applicant argues that the amendments to the claims overcome this grounds of rejection. Applicant's arguments filed 12/31/2001 have been fully considered but they are not persuasive.

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As set forth in the previous office action, it is not clear what would be considered a derivative and what would not. Applicant's amendment does not address this aspect of the rejection. Specifically, it is not clear at what point of difference an "antibody derivative" would cease to be an "antibody derivative" and be considered a different composition altogether.

***Claim Rejections - 35 U.S.C. § 103***

15. Prior to addressing the rejections under 103, it is noted that in the previous Office Action, claims 3, and 8-10 were inadvertently omitted of the rejection statement, though the limitations were specifically addressed in the body of the rejection. They are included in the rejection set forth below.

16. Claims 1-10, and 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nef and Nef, PNAS, Vol. 94, pages 4766-4771, April 1997, or Drutel et al., Receptors and Channels, Vol. 3, pages 33-40, 1995, or Vanderhaeghen et al., Biochemical and Biophysical Research Communications, Vol. 237, pages 283-287, 1997, or Mombaerts et al., Cell, Vol. 87, pages 675-686, November 15, 1996, in view of Janeway and Travers, Immunobiology, pages 2:20-2:30, 1997, or Stites et al., Basic and Clinical Immunology pages 291-293, 1987, or Schlossman et al., Purification of B Lymphocytes, pages 313-315, 1973, or Seed et al., PNAS, Vol. 84, pages 3365-3369, May 1987, or Wysocki et al., PNAS, Vol. 75, No. 6, pages 2844-2848, June 1978, or Aruffo et al., PNAS, Vol. 84, pages 8573-8577, December, 1987, or Heller

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et al., PNAS USA, Vol. 94, pages 2150-2155, March 1997, or Foote, US Patent 5,661,628, August 26, 1997.

As set forth in the previous Office Action, Nef and Nef teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory and neurologic function. Nef and Nef further teach DNA analysis of the olfactory positive cells, including Southern Blot analysis. (see for example, abstract). Drutel et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells function in olfactory development, sperm chemotaxis, and odor and taste recognition (see for example, abstract and page 33, first paragraph). Drutel et al. further teach DNA analysis of the olfactory positive cells. Vanderhaeghen et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory function Vanderhaeghen et al. further teach DNA analysis of the olfactory positive cells. (see for example, abstract) Mombaerts et al. teaches olfactory marker positive cells, and methods of identifying such, and that such cells have olfactory and neurologic function. Mombaerts et al. further teach DNA analysis of the olfactory positive cells (see for example, abstract). Thus olfactory cells and their functions are known in the art.

Nef and Nef, Drutel et al., Vanderhaeghen et al., or Mombaerts et al. fail to teach sorting and enrichment of cells which express olfactory (serpentine) receptors, cell sorting using at least one additional marker, or at least one binding assay, and microchip analysis. The sorting and enrichment of cells which are known to express a receptor, cell sorting using at least one

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additional marker, or at least one binding assay, and microchip analysis, are well known in the art.

Methods of cell sorting, purification and selection based on specific receptor expression are well established in the art. For example, Janeway and Travers, teaches methods of selecting specific cells and purifying those cells using immunohistochemistry, protein affinity purification, and FACS (including multiple markers, immobilized binding agents, multiple binding agents, monoclonal and polyclonal antibodies, as well as DNA analysis) (see pages 2:20-2:30). Stites et al. teaches methods of selecting specific cells and purifying those cells using FACS (including monoclonal and polyclonal antibodies and DNA analysis) (see pages 23291-291). Schlossman et al. teaches methods of sorting and purifying B-lymphocytes using polyclonal antibodies (see page 313). Seed et al. teaches methods of sorting using monoclonal antibodies, as well as DNA analysis and Southern Blot and including the cell adhesion molecule CD2. Wysocki et al. teaches methods of selecting specific cells and purifying those cells using immunohistochemistry, and protein affinity purification (including multiple markers, immobilized binding agents, and polyclonal antibodies) Aruffo et al. teaches methods of sorting using monoclonal antibodies, as well as DNA analysis and Southern Blot, and including the cell adhesion molecule CD2. Heller et al., teaches DNA analysis of selected cells using micro array design. Foote, US Patent 5,661,628 teaches an example a microchip used for DNA analysis and methods of using such. (see for abstract and entire document). Thus the specific methods of sorting and analyzing cells were known in the art, as set forth and exemplified above.



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Therefor it would have been prima facie obvious to one of skill in the art to sort and analyze the olfactory (serpentine) marker expressing cells to obtain an enriched composition, using serpentine receptors, with or without another cell marker, and one would have been motivated to do so to test for olfactory function, sperm chemotaxis, or neurological function, and to use the cells to study these functions and provided treatment which correspond to failures f these systems, as set forth above.

Applicant argues that there is no motivation to combine the references, because there is nothing in the primary references which motivates one to separate cells from a sample. Specifically, applicant argues that the previous motivation provided above would not be sufficient to suggest combining the references, because there is no indication of what type of olfactory or neurologic function might be tested using the cells. Applicant further argues that there is no motivation to sort cells by a second marker in order to obtain an the resulting enriched composition, arguing that prior to the instant application, it was not known that serpentine cell surface receptors constitute the "address molecules" that define cell lineage and provide the high level of specificity required for the formation of complex tissues and organs. Applicant's arguments filed 12/31/2001 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there are a multitude of motivations for sorting cells to obtain an enriched cell population, particularly when the function of the sorted cells is known. For example, sorting cells which express a receptor to study that receptor expression, sorting to obtain a specific cell type which is useful in treatment of a disease, and so forth. For example, cells are often sorted by CD2 in order to obtain a population of cells which are enriched in CD2, to further study CD2 (see for example, Seed et al., cited above, or also see Wysocki et al., also cited above, which teaches at page 2844 that the ability to sort cells by phenotype, by administering antibodies (including different antibodies) to select for specific markers, and thus obtain an enriched population and depleted population is an important development for researching cells function and determining treatments.

In response to applicant's argument that serpentine cell surface receptors constitute the "address molecules" that define cell lineage and provide the high level of specificity required for the formation of complex tissues and organs, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The claims are drawn to methods of sorting cells, to obtain an enriched cell population. Such methods are well established in the art as set forth above, regardless of what type of cell is

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being sorted. Discovery of a previously unknown property of a cell does not make the enrichment of that cell patentable, when the methods of enrichment, the cell itself, and its general function were previously known.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [[anthony.caputa@uspto.gov](mailto:anthony.caputa@uspto.gov)].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set

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forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

April 22, 2002

  
SHEELA HUFF  
PRIMARY EXAMINER